DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5313	12/06-10/2010
	FEI NUMBER 1000117586

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Chinna Pamidi, Ph.D., President

FIRM NAME	STREET ADDRESS
Cetero Research	10550 Rockley Road, Suite 150
CITY, STATE AND ZIP CODE Houston, TX 77099	TYPE OF ESTABLISHMENT INSPECTED Bioanalytical Laboratory

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

"This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above."

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Specifically,

For Study – (b)(4) **and Study** (b)(4) –:

Analysis of the plasma samples test results obtained from Study (b)(4) and Study (b)(4) for (b)(4) from March to June, 2009 using different LC/MS/MS assays revealed the following:

1. Failure to identify and document procedures for "prep" run injections as described in the Form FDA-483 issued to Cetero-Houston on May 7, 2010. Specifically, in Study (b)(4) and Study (b)(4), analytical runs were "prepped" from one to several times using run samples (i.e., samples could be uninjected subject samples, calibration standards and/or quality control samples (QCs), and the number of samples in the "prep" runs varied greatly. No explanation, rationale or justification of how the "prep" runs were carried out was provided by Cetero-Houston. Analysts that conducted the "prep" runs did not follow any written procedure and did not document any of the actions they completed during the performance of the "prep" runs.

2. Review of the records for the extraction of subject samples for the determination of (b)(4) and (b)(4) concentrations in plasma verified that the records were falsified as described in the Form FDA-483 issued to Cetero-Houston on May 7, 2010. Examples include analytical Run 5 and Run 6 for (b)(4), and analytical Run 4 for (b)(4) in Study (b)(4).

3. Stability was not demonstrated under the same conditions as in the study samples. Specifically, samples in stability experiments contained either (b)(4), or (b)(4), whereas study samples in Study contained (b)(4); study samples in Study contained combinations of (b)(4), or (b)(4).

4. Documentation for the re-injections of analytical runs was not contemporaneous. For example, samples in Study (b)(4) Run 5 were analyzed for (b)(4) on April 4, 2009. The majority of samples in Run 5 were re-injected on April 7, 2009. However, there was no documentation at that time to explain or justify these re-injections. Explanation was later provided, during the course of an investigation of allegations of improprieties, in a LC/MS/MS supervisor memo dated September 09, 2009.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE(S)	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Albert F. Peacock, Ph.D., CSO Sam H. Haidar, Ph.D., R.Ph. Martin K. Yau, Ph.D. John A. Kadavil, Ph.D. Xikui Chen, Ph.D.	Albert F. Peacock, Ph.D., CSO Sam H. Haidar, Ph.D., R.Ph., Acting Branch Chief GLP & Bioequivalence Investigations Branch Martin K. Yau, Ph.D., Pharmacologist John A. Kadavil, Ph.D., Pharmacologist Xikui Chen, Ph.D. Chemist	12/10/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

For Study [redacted] – (b)(4) and Study [redacted] - (b)(4) :

Analysis of the plasma samples test results obtained from Study (b)(4) (subject sample analysis from 9/12/09 to 10/09/09) and Study (b)(4) (subject sample analysis from 11/10/09 to 11/17/09) revealed the following:

5. Prior to 35 out of 36 subject sample runs in Study (b)(4), and prior to 12 out of 14 subject sample runs in Study (b)(4), runs using "equilibration samples" were performed. Electronic records of chromatography acquisition for "equilibration samples" are maintained in "EQUILIBRATE" file folders. For these "equilibration" runs, the firm did not:

   a) Establish written procedures specifying the types of samples to be used in "equilibration" runs and the purpose of these runs. The firm subsequently implemented an SOP for equilibration of LC/MS/MS instruments on 12/14/09.

   b) Maintain documentation confirming the actual identity of the "equilibration samples".

   c) Maintain documentation justifying the number of injections of "equilibration samples". The number of sample injections varied between each "equilibration" run, and ranged from 4 injections to as many as 43 injections. In several "equilibration" runs, specific samples were repeatedly injected. For example, in EQrun 9 for Study (b)(4), the injections were Sample001 to Sample020, Sample001 to Sample006, Sample001 to Sample007, Sample001, Sample002, and finally Sample001.

6. Failure to adequately document all aspects of study conduct in Study (b)(4) and Study (b)(4). Specifically:

   a) The storage location for the aliquots of standards and QC samples were not recorded.

   b) Sample tracking for aliquots of standards and QC samples generated from bulk preparations was not recorded.

   c) Preparation of the internal standard solutions was not clearly referenced in the Analytical Procedure Form for Runs 1-16 in Study (b)(4).

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